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| 10/507,061 | 08/03/2005 | Gerold Lukowski | F-8379 | 8844 |

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| EXAMINER | |
|---|---|
| ARIANI, KADE | |

| ART UNIT | PAPER NUMBER |
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| 1651 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/507,061 | LUKOWSKI ET AL. | |
| | Examiner | Art Unit | |
| | Kade Ariani | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-37 is/are rejected.

7)☒ Claim(s) 2, and 5-15 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## *DETAILED ACTION*

The preliminary amendment filed on April 11, 2005, has been received and entered.

Claims 1-37 are pending in this application and were examined on their merits.

### *Claims and Specification*

The disclosure is objected to because of the following informalities:

The word --characterized -- is misspelled as "characterised" in claims 2, and 5-15 and in specification (page 2 line 26), also the word --homogenization-- is misspelled as "homogenization" in claims 10, 11, 14, and 15, and all through the specification (pages 5-8, 15-19, 23, and 26-29).

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 10, 13, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9, 10 and 37 are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

The recitation ".... dispersed under addition of a little quantity of water " in claim 13, is indefinite because it is not clear how much water should be added in for the active substances to be dispersed.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16-37 provide for the use of biomass of lipid-containing marine organisms, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 16-37 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Müller et al. (European Journal of Pharmaceutics and Biopharamaceutics, 2000, Vol. 50, p. 161-177) in view of Kreitlow et al. (Journal of biotechnology, 1999, Vol. 70, p. 61-163) and in view of Caudales et al. (International Journal of Systematic and Evolutionary Microbiology, 200,50 p.1029-1034) and further in view of Viseras et al. (International Journal of Pharmaceutics, 1999, Vol. 182, p.7-20) and further in view of Jacob et al. (Life sciences, Vol. 66, No. 25, p. 2433-2439) and further in view of Walker et al. (New Zealand Journal of Botany, 1997, Vol. 35, p. 396-384),and further in view of Chairungsrilerd et al. (European Journal of Pharmacology, 1996, Vol. 314, p. 351-356).

Claims 1-10, and 16-37 are drawn to a pharmaceutically or cosmetically active agents, obtained by the conversion of biomasses consisting of lipid-containing marine organisms into micro and nanoparticles, contain one or more pharmaceutical or cosmetic active substances, marine organisms cyanobacteria from class *Oscillatoriales*, and/or the class *Nostocales*, and use of (biomass of lipid-containing marine

microorganisms in the form of) macro- and nanoparticles as carrier for active substances, cosmetics o, pharmaceuticals, bactericidal agents.

Müller et al. teaches pharmaceutically active agents consisting of solid lipid nanoparticles (SNL) with a diameter of 10nm to 10 μm, (p. 162, column 2, line 2), and the use of solid lipid nanoparticles as a matrix material for drug delivery, vitamin, ubiquinones (Coenzyme Q10), radical scavenger, dietary supplements (p.164, Table 1.)

Claims 11-15 are drawn to a method for the production of pharmaceutically or cosmetically active agents (according to claim 1 or 2), homogenization of biomasses of lipid-containing marine organisms into micro- and nanoparticles with a diameter of 10nm to 10 μm (1000nm), heating until the liquefaction of the fatty acids contained therein, mixing with a surfactant-water mixture heated to a temperature above the fatty acids melting points and unification of the two phases, preparation of pre-suspension, and high pressure homogenization, heating of the microorganisms and the surfactant-water mixture is omitted, and active substances are adsorbed at room temperature or dispersed, spray drying or lyophilization.

Müller et al. teaches a method for the production of pharmaceutically or cosmetically active agents, homogenization or emulsification into micro- and nanoparticles with a diameter of 10nm to 10 μm (1000nm), heating the lipids until the liquefaction, optionally adding one or more active substances or additives, mixing the with a surfactant-water mixture heated to a temperature above the fatty acids melting points and unification of the two phases, preparation of pre-suspension, and high pressure homogenization in one or more homogenization cycles, heating of the lipids

and the surfactant-water mixture is omitted (cold homogenization), and active substances are adsorbed at room temperature or dispersed, (p. 162, column 1, 3rd and 4th paragraphs and column 2, 1st and 2nd paragraphs, p. 163, column 1, lines 6-15, and last paragraph, p. 166, column 1, last 3 lines), subsequent spray drying or lyophilization (p. 171, column 2, part 9., lines 6-14), formation of an emulsion of water and lipids, dissolving the emulsion in an appropriate organic solvent, (p. 164, column 1, 2nd paragraph, lines 4-8).

Müller et al. does not teach lipid nanoparticles obtained from biomasses of lipid-containing marine organisms, adding clay mineral, adding xanthones derivatives, and norlichexanthone. However, Kreitlow et al. teaches biomasses consisting of lipid-containing cyanobacteria strains (*Oscillatoriales, Chroococcales, Nostocales*), and screening the antibacterial and antifungal activities of the lipophilic extracts obtained from cyanobacterial biomass, Kreitlow et al. further teaches lipophilic extracts inhibited the growth of *S. aureus* (Abstract, p. 62, column 1, and column 2, 2nd paragraph, lines 15-17).

Caudales et al. teaches the fatty acid composition of different strains of cyanobacteria, high proportions of saturated straight chain and unsaturated straight chain fatty acids, mono- and poly-unsaturated fatty acids, and also fatty acids of different chain length (see Table 1.).

Müller et al. also teaches "the prerequisite to obtain a sufficient loading capacity is a sufficiently high solubility of the drugs in the lipid melt, the presence of mono- and diglycerides in the lipid used as matrix promotes drug solubilization" and further teaches

"polymorphic state of lipid material is one of the factors determining the loading capacity of drug in the lipid, also the chemical nature of the lipid is important because lipids which from highly crystalline particles with a perfect lattice, lead to drug expulsion. More complex lipids being mixtures of mono-, di- and triglycerides and also containing fatty acids of different chain length form less perfect crystals with many imperfections offering space to accommodate the drugs. Chemically polydisperse lipids such those used in cosmetics showed very good drug incorporation capacities" (p.164 column 1, last 2 paragraphs, column 2, lines 1-9, and p.165 column 1, lines 1-2).

Moreover, Viseras et al. teaches phyllosilicates and fibrous clay among the most widely used minerals in the composition of medicines (see Introduction, column 1, lines 1-14). Chairungsrilerd et al. teaches xanthone derivative, alpha-mangostin, and its anti-inflammatory properties (See Introduction and p.352, Figure 1.), Walker et al. teaches biologically active compounds of lichens used in folk medicine, especially norlichexanthones (see Introduction and p. 347, column 2, end paragraph and p. 374, column 1), and Jacob et al. teaches antifungal and antibacterial properties of thiocayanate. Also, cosmetic or pharmaceutical compositions in forms of oils, sprays, and ointments are very well known in the art.

Therefore, it would have been obvious to one of ordinary skill in the art to use the method as taught by Müller et al. to convert lipid extracts (with antibacterial and antifungal activities) of marine organisms as taught by Kreitlow et al. into micro- and nanoparticles in an attempt to provide pharmaceutically (or cosmetically) active agents, with antibacterial and antifungal activities, and cyanobacteria strains have mixture of

lipids and fatty acids of different chain length, and in order to gain the commonly understood benefits of obtaining solid lipid nanoparticles with better solubility and very good drug incorporation capacities. Also, because the pharmaceutically active agents, as claimed have the properties predicted by the art, it would have been obvious to make such pharmaceutically active agents.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

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Kade Ariani
Examiner
Art Unit 1651

Leon B. Lankford Jr.
Primary Examiner
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